

CLAIMS

What is claimed is:

1. A pharmaceutical composition in a solid oral dosage form comprising:
 - 5 a core containing a therapeutically effective amount of at least one conjugated estrogen, or a component thereof, and at least one organic excipient, wherein the at least one organic excipient comprises less than about 25% w/w of a cellulose ingredient, and less than about 50% w/w of a sugar ingredient, and at least one inorganic excipient, wherein the at least one inorganic excipient includes a calcium phosphate tribasic
 - 10 ingredient in an amount of less than about 20% w/w; and
a pharmaceutically acceptable coating that is free of hormones, wherein the composition does not crack when stored at 40 °C and 75% relative humidity for about two months.
- 15 2. The pharmaceutical composition of claim 1, wherein the therapeutically effective amount of conjugated estrogen is from about 0.1 mg to about 3 mg.
3. The pharmaceutical composition of claim 2, wherein the amount is about 0.625 mg.
- 20 4. The pharmaceutical composition of claim 1, wherein the coating is a sugar coating.
5. The pharmaceutical composition of claim 1, wherein the coating is an acrylic
- 25 coating.
6. The pharmaceutical composition of claim 1, wherein the sugar ingredient is present in an amount of from about 5% w/w to about 50% w/w.
- 30 7. The pharmaceutical composition of claim 1, wherein the sugar ingredient is present in an amount of from about 10% w/w to about 40% w/w.
8. The pharmaceutical composition of claim 1, wherein the sugar ingredient is

present in an amount of from about 20% w/w to about 30% w/w.

9. The pharmaceutical composition of claim 1, wherein the calcium phosphate tribasic ingredient is present in amount of from about 1% w/w to about 15% w/w.

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10. The pharmaceutical composition of claim 1, wherein the calcium phosphate tribasic ingredient is present in amount of from about 5% w/w to about 15% w/w.

11. The pharmaceutical composition of claim 1, wherein the calcium phosphate tribasic ingredient is present in amount of from about 1% w/w to about 10% w/w.

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12. The pharmaceutical composition of claim 1, wherein the calcium phosphate tribasic ingredient is present in an amount of from about 5% w/w to about 10% w/w.

13. The pharmaceutical composition of claim 1, wherein the conjugated estrogen is of a natural origin.

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14. The pharmaceutical composition of claim 1, wherein the conjugated estrogen is of a synthetic origin.

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15. The pharmaceutical composition of claim 1, wherein the conjugated estrogen is a mixture of estrogenic components.

16. The pharmaceutical composition of claim 1, wherein the conjugated estrogen is an ester of an estrogen.

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17. The pharmaceutical composition of claim 1, wherein the cellulose ingredient is a member selected from the group consisting essentially of: hydroxypropyl cellulose, carboxymethylcellulose, ethyl cellulose, methyl cellulose, salts thereof, derivatives thereof, and mixtures thereof.

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18. The pharmaceutical composition of claim 17, wherein the cellulose ingredient is hydroxypropyl cellulose.

19. The pharmaceutical composition of claim 1, wherein the sugar ingredient is a member selected from the group consisting essentially of: sucrose, glucose, mannose, fructose, lactose, and mixtures thereof.

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20. The pharmaceutical composition of claim 19, wherein the sugar ingredient is sucrose.

21. The pharmaceutical composition of claim 20, wherein the sucrose is derived from
10 a source selected from the group consisting essentially of: beet sources, cane sources, starch, saccharide converted sources, polysaccharide converted sources, and mixtures thereof.

22. The pharmaceutical composition of claim 21, wherein the sucrose is derived from
15 cane sources.